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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/288,719	04/09/99	KONTERMANN R	26083/201

HM12/1004

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EXAMINER	
BECKERLEG, A	

ART UNIT	PAPER NUMBER
1632	13

DATE MAILED: 10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

RLO

Office Action Summary

Application No.	Applicant(s)
09/288,719	Kontermann et al.
Examiner	**Group Art Unit**
Anne Marie S. Beckerleg	1632

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-82* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-82* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-55, 72, and 76-78, drawn to single-chain binding molecule, pharmaceutical compositions of the binding molecules, diagnostic aids comprising the binding molecules and methods of diagnosis or treatment using said binding molecules, classified in classes 435, 514, and 530 , subclasses 4, 2, and 300 or 350 respectively .

II. Claims 56-71, 72-75, 79-82, drawn to nucleic acids, vectors, and cells, pharmaceutical compositions of nucleic acids, vectors, or cells, diagnostic aids comprising nucleic acids, vectors or cells, and methods of diagnosis or treatment using said nucleic acids, vectors or cells, classified in classes 424, 435, 514, and 536, subclasses 93.21, 6 and 435 and 320.1, 44, and 26.1 respectively.

The inventions are distinct, each from the other, because the nucleic acid encoding a single chain binding molecule and the vectors and cells comprising said nucleic acids of invention II and the single chain binding molecule of invention I are significantly different in physical and chemical structure, properties, and activity, are made using substantially different techniques, and can be used for substantially different purposes for which the other product is not required. In particular, it is noted that the use of nucleic acids for diagnostic purposes utilizes substantially different

methods than those which employ proteins, such as PCR, Northern, or Southern hybridization. In addition, the biological properties and activity of polypeptides and nucleic acids differs substantially, particularly in an *in vivo* environment. The administration of polypeptides versus nucleic acids *in vivo* is complicated by different factors, such as the stability and half-life of an administered polypeptide in the host versus the transformation efficiency and stability of gene expression of nucleic acids in particular cells types in vivo.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different search requirements, and different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to patentably distinct species.

1) For inventions I and II, the applicant claims patentably distinct species for the first specificity

(A) of the antigen binding molecule as follows:

a) the cell membrane of a target cell

b) a molecule to be analyzed

c) a protein of the extracellular matrix

d) a protein of the complement system

e) a protein of the coagulation system

f) a protein of the kinin system

g) a protein of blood plasma

h) a protein of the supporting tissue

i) a cytokine

j) a chemokine

k) an endogenous or exogenous toxin

l) a pharmaceutical

m) a pathogen

2) For inventions I and II, the applicant claims patentably distinct species for the second specificity (B) of the antigen binding molecule as follows:

a) an analyte

b) a molecule to be analyzed

c) a vector

d) a cell membrane

e) a protein of the complement system

f) a protein of the coagulation system

g) a fibrinolytic protein

h) a cytokine

i) a chemokine

j) a growth factor

k) an endogenous or exogenous toxin

l) digitonin

m) a pathogen

n) a prodrug activating enzyme

o) a peptide or steroid hormone

p) the constant part of an immunoglobulin

q) a mediator

r) a tumor cell

3) For inventions I and II, the applicant claims patentably distinct species for the effector (E) of the antigen binding molecule as follows:

a) a transmembrane domain

b) a glycophospholipid anchor

c) the ligand-binding part of a receptor

d) a ligand for a receptor

e) the receptor-binding part of a ligand

f) a peptide hormone

g) a cytokine

h) a growth factor

i) a growth factor inhibitor

j) a chemokine

k) an interferon

l) a mediator

m) a peptide acting on the circulation

n) a prodrug activating enzyme

o) a protein which activates coagulation

p) a protein which inhibits coagulation

q) a protein which activates fibrinolysis

r) a protein which inhibits fibrinolysis

s) a protein which activates complement

t) a protein which inhibits complement

u) a constant domain of an immunoglobulin

v) a cytotoxic peptide

w) a single-chain antigen-binding molecule

x) a tumor antigen

y) a pathogenic antigen

z) a peptide comprising cysteine

aa) a di-or multimerizing peptide

bb) a fusogenic peptide

4) For inventions I and II, the applicant claims patentably distinct species for using the single-chain multiple antigen binding molecule or nucleic acid encoding the molecule as follows:

a) diagnosis of cancer

b) diagnosis of autoimmune disease

c) diagnosis of inflammatory disease

d) diagnosis of disorders of the blood

e) diagnosis of disorders of the nervous system

f) diagnosis of infectious diseases

g) prophylaxis or treatment of cancer

h) prophylaxis or treatment of autoimmune disease

i) prophylaxis or treatment of inflammatory disease

j) prophylaxis or treatment of disorders of the blood

k) prophylaxis or treatment of disorders of the nervous system

l) prophylaxis or treatment of infectious diseases

It is particularly noted that methods of diagnosis and methods of treatment using proteins or nucleic acids are substantially different in that the methods of diagnosis do not require any therapeutic activity on the part of the protein or nucleic acid and are generally conducted *in vitro* under non-physiological conditions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of groups 1)- 4) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-18, 23, 72, and 78 are generic to invention I and claims 56-71, 73-75, and 79-82 are generic to invention II.

Applicant is advised that a response to this requirement must include and election of inventions I or II and an identification of the species that is elected for each of group 1) species a) - m), group 2) species a)-r), group 3) species a)-bb), and group 4) species a)-l) consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to on to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 8:30-6:00. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The official fax number is (703) 308-4242.

Karen M. Hauda

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